



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0389]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0154. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles--21 CFR Part 226 (OMB Control Number 0910-0154)--Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for Type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)). Under part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing) and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP

criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the FD&C Act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act. The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs, and commercial feed mills.

In the Federal Register of April 7, 2014 (79 FR 19093), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours
226.42	65	260	16,900	0.75 (45 minutes)	12,675
226.58	65	260	16,900	1.75	29,575
226.80	65	260	16,900	0.75 (45 minutes)	12,675
226.102	65	260	16,900	1.75	29,575
226.110	65	260	16,900	0.25 (15 minutes)	4,225
226.115	65	10	650	0.5 (30 minutes)	325
Total					89,050

¹There are no capital costs or operating and maintenance costs associated with this collection.

The estimate of time required for record preparation and maintenance is based on previous Agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from Agency records and experience.

Dated: June 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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